

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA,

v.

14-CV-0053-A

FINGER LAKES FARMSTEAD CHEESE
COMPANY, a limited liability company,
and
NANCY TABER RICHARDS, an individual,
Defendants

JOINT MOTION TO ENTER CONSENT DECREE OF PERMANENT INJUNCTION

Upon the attached Affidavit of Gretchen L. Wylegala, Assistant United States Attorney, sworn to on the 20th day of March, 2014, the parties hereby respectfully request that this Court sign and enter the Consent Decree of Permanent Injunction ("Consent Decree") attached to this motion. All parties have agreed to the entry of the attached Consent Decree, as evidenced by their signatures. Accordingly, the parties request that the Court sign and enter the Consent Decree as its final Order in this case.

DATED: Buffalo, New York, March 20, 2014

Respectfully submitted,

WILLIAM J. HOCHUL, JR.
United States Attorney

BY: S/Gretchen L. Wylegala
GRETCHEN L. WYLEGALA
Assistant United States Attorney
United States Attorney's Office
Western District of New York
138 Delaware Avenue
Buffalo, New York 14202
(716) 843-5700 ext. 822
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Of Counsel:
WILLIAM B. SCHULTZ
General Counsel

ELIZABETH DICKINSON
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Food and Drug Division

ANNAMARIE KEMPIC
Deputy Chief Counsel, Litigation

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United States Department of
Health and Human Services
Office of the General Counsel,
Food and Drug Division
10903 New Hampshire Avenue
Silver Spring, MD 20993
301-796-8593

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14-CV-0053-A

FINGER LAKES FARMSTEAD CHEESE
COMPANY, a limited liability company,
and
NANCY TABER RICHARDS, an individual,
Defendants

AFFIDAVIT

STATE OF NEW YORK)
COUNTY OF ERIE)
CITY OF BUFFALO) SS:

I, Gretchen L. Wylegala, hereby depose and state as follows:

1. I am the Assistant United States Attorney assigned responsibility for the above-captioned case.
2. The purpose of this Affidavit is to obtain an order of the Court approving and entering the attached Consent Decree of Permanent Injunction. The Consent Decree is attached as Exhibit A.
3. On January 22, 2014, the United States filed a Complaint for Injunction against Finger Lakes Farmstead Cheese Company, a limited liability company and Nancy Taber Richards, an individual.
4. On January 22, 2014, the parties also entered into a Consent Decree

settling this case, and agreeing to the entry of the Consent Decree, as evidenced by their signatures.

5. On March 13, 2014, the United States filed the waivers of service provided on behalf of both defendants. (Dkt. 3 and 4)
6. Jeffrey Walker, Esq., counsel for both Finger Lakes Farmstead Cheese and Nancy Taber Richards, who is admitted in the Northern District of New York, has applied for admission into the Western District of New York, and is waiting for confirmation of that admission.
7. I have communicated with Mr. Walker, and he indicates he consents to the filing of this motion, and the entry of the Consent Decree.

WHEREFORE, the parties move this Court for an Order approving and entering the Consent Decree as its final Order in this case.

S/Gretchen L. Wylegala
GRETCHEN L. WYLEGALA
Assistant United States Attorney

Sworn to before me this 20th day
of March, 2014.

S/Cheryl Kinmartin
COMMISSIONER OF DEEDS
In And For The City Of Buffalo, NY
My Commission Expires Dec. 31, 2014.

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA,

v.

14-CV-0053-A

FINGER LAKES FARMSTEAD CHEESE
COMPANY, a limited liability company,
and
NANCY TABER RICHARDS, an individual,
Defendants

CERTIFICATE OF SERVICE

I hereby certify that on March 20, 2014, I electronically filed the foregoing **JOINT MOTION TO ENTER CONSENT DECREE OF PERMANENT INJUNCTION** with the Clerk of the District Court using its CM/ECF system.

I further certify that on March 20, 2014, I mailed the foregoing **JOINT MOTION TO ENTER CONSENT DECREE OF PERMANENT INJUNCTION** by the United States

Postal Service, to:

Jeffrey D. Walker, Esq.
SCHLATHER, STUMBAR, PARKS & SALK, LLP
200 East Buffalo Street
P.O. BOX 353
Ithaca, New York 14851-0353

S/Cheryl Kinmartin
Cheryl Kinmartin

EXHIBIT A

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA,)

Plaintiff,)

v.)

FINGER LAKES FARMSTEAD)
CHEESE COMPANY,)
a limited liability company,)

and)

NANCY TABER RICHARDS,)
an individual,)

Defendants.)
_____)

Civil No. _____

CONSENT DECREE OF
PERMANENT INJUNCTION

Plaintiff, United States of America, by its undersigned attorneys, having filed a complaint for permanent injunctive relief against Finger Lakes Farmstead Cheese Company, a limited liability company, and Nancy Taber Richards, an individual (collectively "Defendants"), and Defendants having appeared and consented to entry of this Consent Decree of Permanent Injunction ("Decree") without contest and before any testimony has been taken, and the United States of America having consented to this Decree,

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that:

1. This Court has jurisdiction over the subject matter and over all parties to this action.

2. The Complaint for Permanent Injunction states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 301 et seq.

3. Defendants violate the Act, 21 U.S.C. § 331(k), by adulterating, or causing the adulteration of, articles of food within the meaning of 21 U.S.C. § 342(a)(1) and 21 U.S.C. 342(a)(4) while such articles are held for sale after shipment of one or more ingredients in interstate commerce.

4. Defendants and each and all of their officers, agents, employees, representatives, successors, assigns, heirs, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) are hereby permanently restrained and enjoined, under the provisions of 21 U.S.C. § 332(a) and the equitable authority of this Court, from directly or indirectly receiving, preparing, processing, packing, holding, and distributing articles of food, at or from their facility located at 5491 Bergen Road, Trumansburg, New York 14886-9674 (the "Finger Lakes facility"), and any other locations at or from which Defendants, now or in the future, receive, prepare, process, pack, hold, or distribute any articles of food, unless and until:

A. Defendants retain, at their expense, an independent laboratory (the "laboratory") having no personal or financial

ties (other than the retention agreement) to Defendants or their families, which is qualified to collect product and environmental samples from within the Finger Lakes facility and analyze those samples for the presence of *Listeria monocytogenes* ("L. mono") in a method that is acceptable to the United States Food and Drug Administration ("FDA"). Defendants shall notify FDA in writing immediately upon retaining such laboratory and shall provide FDA a copy of the service contract. Such service contract shall contain certain provisions, acceptable to FDA, for regular environmental and finished product sample collection and analyses, including how and where to sample, the number and frequency of samples to be collected, and the methods of analyses, in accordance with the Listeria Monitoring Program discussed in paragraph 4(C) below;

B. Defendants retain, at their expense, an independent expert(s) (the "sanitation expert") having no personal or financial ties (other than the retention agreement) to Defendants or their families, and who, by reason of background, education, training, and experience, is qualified to inspect Defendants' facility and to determine whether the methods, facilities, and controls are operated and administered in conformity with the Act and 21 C.F.R. Part 110. Defendants shall notify FDA in writing of the name(s) and qualifications of the sanitation expert(s) as soon as they retain such expert(s).

C. Defendants' sanitation expert, in consultation with the laboratory, after review of all FDA observations from June 1, 2012 to present, develops a written *Listeria* Monitoring Program, which shall include, at a minimum, the following:

(1) An effective written sanitation control program that establishes adequate methods, facilities, and controls for receiving, preparing, processing, packing, holding, and distributing articles of food to minimize the risk of introduction of *L. mono*, other pathogenic organisms, or filth into Defendants' food, and to ensure that foods are not adulterated, within the meaning of 21 U.S.C. § 342(a). Such methods, facilities, and controls shall include, but shall not be limited to, thoroughly cleaning, sanitizing, renovating, and rendering the Finger Lakes facility and all equipment therein suitable for use in receiving, preparing, processing, packing, holding, and distributing articles of food to prevent such articles from becoming adulterated, and instituting standard sanitation operating procedures ("SSOPs") to ensure that the Finger Lakes facility and equipment therein are continuously maintained in a sanitary condition;

(2) A written employee training program that includes, at a minimum, instruction on sanitary food handling techniques and documentation that each employee has received such training.

Defendants' expert shall ensure that each employee fully understands the substance of the employee training program;

(3) An effective program of environmental monitoring and testing of the Finger Lakes facility to ensure that such pathogenic organisms as *Listeria species* (*L. spp.*) are controlled, and such substances, including *L. mono*, are not present within the facility. Environmental monitoring shall include, but not be limited to, collecting swab samples from food-contact surfaces, equipment, and other environmental sites throughout the Finger Lakes facility (where the raw ingredients, in-process, and finished articles of foods are received, prepared, processed, packed, held, and/or distributed, and common areas that could be reservoirs for cross-contamination), and analysis of collected samples, in a manner acceptable to FDA. Defendants shall ensure that the results of all analyses conducted pursuant to this paragraph are sent to FDA within two (2) calendar days of receipt by Defendants; and

(4) A written plan for remedial action should *L. spp.*, *L. mono*, or any other pathogenic organisms be detected;

D. Defendants assign continuing responsibility for the operation of the *Listeria* Monitoring Program to a person or persons who, by reason of background, experience, or education, is competent to maintain the Finger Lakes facility in a sanitary condition, coordinate with the laboratory, and implement any

necessary remedial action(s), and provide such person with the authority to achieve the necessary corrections;

E. FDA approves, in writing, the *Listeria* Monitoring Program discussed in paragraph 4(C) prior to implementation;

F. The sanitation expert conducts a comprehensive inspection of the Finger Lakes facility and the methods and controls used to receive, prepare, process, pack, hold, and distribute foods to determine whether Defendants have effectively implemented all necessary corrections and are operating in compliance with this Decree, the Act, and 21 C.F.R. Part 110. The expert shall submit all findings to Defendants and FDA concurrently, within ten (10) business days of completion of the inspection;

G. Defendants report to FDA in writing the actions they have taken to bring their operations into compliance with the Act and all applicable regulations, including:

(1) Documentation that Defendants have cleaned and sanitized the Finger Lakes facility and equipment therein and made improvements, thereby rendering the facility and equipment suitable for receiving, processing, preparing, packing, holding, and distributing articles of food, and documentation that Defendants have conducted environmental testing in a manner acceptable to FDA and received laboratory results showing that *L. mono* is no longer present in the facility;

(2) Specific measures that they have taken to address each of the violations documented by FDA since June 1, 2013; and

(3) A copy of the *Listeria* Monitoring Program;

H. Within thirty (30) calendar days upon entry of this Decree, Defendants destroy, under FDA's supervision, and according to a destruction plan submitted in writing by Defendants and approved in writing by FDA prior to implementation, all in-process and finished articles of food currently in their custody, control, or possession.

Alternatively, Defendants may retain and distribute such articles if Defendants: (1) submit a written proposal ("reconditioning proposal") that demonstrates that all articles not subject to a destruction plan are either free of pathogenic organisms or will be subjected by Defendants to a process that renders the articles free of pathogenic organisms before distribution; (2) receive written approval of such plan from FDA; and (3) receive written authorization from FDA that the articles may be distributed;

I. FDA, as it deems necessary to evaluate Defendants' compliance with the terms of this Decree, the Act, and all applicable regulations, conducts inspections of the Finger Lakes facility, including the buildings, sanitation-related systems, equipment, utensils, all articles of food, and relevant records contained therein;

J. FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements set forth in paragraph 4 (A) through (H) of this Decree, the Act, and 21 C.F.R. Part 110; and

K. Defendants have paid all costs of inspection, analyses, review, investigations, examination, and supervision for FDA's oversight with respect to paragraph 4 (A) through (I), at the rates set forth in paragraph 10 below.

5. Defendants and each and all of their officers, agents, employees, representatives, successors, assigns, heirs, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) who receive actual notice of this Decree pursuant to paragraph 16 below, are permanently restrained and enjoined under the provisions of 21 U.S.C. § 332(a) from directly or indirectly doing or causing any act that violates the Act, 21 U.S.C. § 331(k), by causing articles of food to be adulterated within the meaning of 21 U.S.C. § 342(a)(4) while such articles are held for sale after shipment of one or more ingredients in interstate commerce; or results in the failure to implement and continuously maintain the requirements of this Decree.

6. Immediately upon resuming operations after completing the requirements of paragraph 4, Defendants shall, in

consultation with the laboratory and the sanitation expert, continuously implement the following steps to prevent further contamination from *L. mono*, other pathogenic organisms, or filth in their food products and facility:

A. Effectively implement, on an ongoing basis, the *Listeria* Monitoring Program developed pursuant to paragraph 4 (C).

B. Conduct environmental monitoring and testing to ensure that the SSOPs continue to eliminate the *L. mono* hazard and that the SSOPs are consistently being followed. Environmental monitoring shall include collecting swab samples from food-contact and non-food-contact surfaces, equipment, and other environmental sites throughout the Finger Lakes facility (where articles of food are received, prepared, processed, packed, and held, up to and including final packaging, as well as common areas), and analyzing such samples for the presence of *L. spp*. Environmental testing for *L. spp* shall be performed by the laboratory in accordance with timetables and methods that Defendants submit to FDA in writing for approval by FDA in writing before testing begins. Defendants shall ensure that the results of all testing conducted pursuant to this paragraph are forwarded to FDA within two (2) calendar days after receipt by Defendants.

Defendants' environmental testing must include, at a minimum, all of the following:

(1) if a non-food-contact surface that is not in close proximity to food (*i.e.*, an area commonly identified by industry as zone 3 or zone 4, including offices, floor drains, locker rooms, and hallways) is found to be positive for *L. spp.* during routine testing, intensified sanitation measures must be initiated as soon as possible;

(2) if a food-contact surface (*i.e.*, an area commonly identified by industry as zone 1, including conveyors, table tops, racks, vats, pumps, slicers, utensils, gloves, and packaging machines) or non-food contact surface that is in close proximity to food (*i.e.*, an area commonly identified by industry as zone 2, including the sides and exterior of processing equipment, refrigeration units, table legs, cart legs, and floor scrubbers) is found to be positive for *L. spp.* during routine testing, intensified sampling must be initiated as soon as possible, in conjunction with intensified sanitation measures. Intensified sampling requires that three (3) samples per day must be collected and analyzed until a total of nine (9) consecutive samples (three (3) days of intensified sampling) have been taken and are negative for *L. spp.* from the site where the *L. spp.* was identified. After nine (9) consecutive samples

are tested and found to be negative, that site may be subject to routine sampling; and

(3) all food products in contact with a site that tests positive for the general strain *L. spp.* must be placed on hold pending laboratory test results. The products can be released if laboratory test results are negative for *L. mono*; if the laboratory results are positive for *L. mono*, all food products manufactured from the time the laboratory sample(s) testing positive for *L. mono* were collected must be destroyed at Defendants' expense, under FDA's supervision, and according to a destruction plan submitted in writing by Defendants and approved prior to implementation, in writing, by FDA; and

C. Conduct finished product testing in the following manner:

(1) Defendants shall test for *L. mono* and *Escherichia coli* ("*E. coli*") in all lots of each food product for at least five consecutive production days using a testing method approved in advance by FDA;

(2) After the completion of testing under paragraph 6(C)(1), Defendants shall test at least one lot of each food product per day for the next twenty (20) production days;

(3) After the completion of testing under paragraph 6(C)(2), Defendants shall test at least one lot of each food

product per every five (5) production days for the next three (3) months; and

(4) After the completion of testing under paragraph 6(C)(3), Defendants shall test at least one lot of each food product per month thereafter.

(5) If any laboratory test completed pursuant to paragraphs 6(C)(1)-(4) shows the presence of pathogens, including *L. mono*, or non-pathogenic *E. coli* at levels greater than 10 most probable number (MPN) per gram in two or more subsamples, or greater than 100 MPN per gram in one or more subsamples, in any article of food, then Defendants must immediately cease production and notify FDA that production has ceased. Defendants shall also destroy, at Defendants' expense, under FDA's supervision, and according to a destruction plan submitted in writing by Defendants and approved prior to implementation, in writing, by FDA, all food products manufactured from the time the laboratory sample(s) testing positive for pathogens including *L. mono*, or non-pathogenic *E. coli* at levels greater than 10 most probable number (MPN) per gram in two or more subsamples, or greater than 100 MPN per gram in one or more subsamples. Defendants may resume production only when they have determined and corrected the cause of the contamination and only after FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements

of this Decree, the Act, and 21 C.F.R. Part 110. After correcting the cause of the contamination, Defendants shall reinstate the complete sequence of testing under this paragraph anew. Defendants shall ensure that the results of all testing conducted pursuant to this paragraph are forwarded to FDA within two (2) calendar days after receipt by Defendants.

7. If, after notifying FDA of the name of the laboratory retained to conduct sample collection and analyses pursuant to paragraph 4(A), Defendants terminate or alter their service contract with the laboratory in any way, Defendants shall notify FDA within five (5) business days. If Defendants terminate their service contract, Defendants shall provide a copy of the service contract with the new laboratory to FDA within of execution.

8. FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of the Finger Lakes facility, and any other locations at which Defendants receive, prepare, process, pack, hold, or distribute articles of food and, without prior notice, to take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree, the Act, and its implementing regulations. During the inspections, FDA shall be permitted to have immediate access to buildings, equipment, raw ingredients, in-process and finished articles of food, containers, and packaging material

therein; to take photographs and make video recordings; to take samples of Defendants' raw ingredients, in-process, and finished articles of food, containers, and packaging material; and to examine and copy all records related to receiving, preparing, processing, packing, holding, and distributing any and all articles of food. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is apart from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

9. Defendants shall notify FDA in writing at least fifteen (15) calendar days before any change in ownership, name, or character of their business, including reorganization, relocation, dissolution, assignment, or lease or sale of the business or any assets of the business, such as buildings, equipment, or inventory, that may affect compliance with the obligations arising from this Decree. Defendants shall provide any prospective successor or assign with a copy of this Decree at least ten (10) calendar days before the assignment or change in business, and shall provide FDA with an affidavit of compliance with this paragraph within ten (10) calendar days of providing a copy of this Decree to a prospective successor or assign.

10. Defendants shall pay all costs of FDA's supervision, inspections, investigations, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with this Decree, at the standard rates prevailing at the time the costs are incurred, and Defendants shall make payment in full to FDA within thirty (30) calendar days of receiving written notification from FDA of the costs. As of the date that this Decree is signed by the parties, these rates are: \$87.57 per hour and fraction thereof per representative for inspection work; \$104.96 per hour or fraction thereof per representative for analytical or review work; \$0.565 per mile for travel by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per representative and per day for subsistence expenses, where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

11. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, sample analyses, or other information, that Defendants have failed to comply with any provision of this Decree, have violated the Act or its implementing regulations, or that additional corrective

actions are necessary to achieve compliance with this Decree, the Act, or its implementing regulations, FDA may, as and when it deems necessary, notify Defendants in writing and order Defendants to take appropriate action, including, but not limited to, ordering Defendants to immediately take one or more of the following actions:

- A. Cease receiving, preparing, processing, packing, holding, and distributing any articles of food;
- B. Recall all articles of food that have been distributed or are under the custody and control of Defendants' agents, distributors, customers, or consumers;
- C. Submit samples of articles of food to a qualified laboratory to determine whether they are contaminated with chemicals, toxins, microorganisms, or filth; and/or
- D. Take any other corrective actions as FDA deems necessary to bring Defendants into compliance with this Decree, the Act, and its implementing regulations.

The provisions of this paragraph shall be separate and apart from, and in addition to, all other remedies available to FDA. Defendants shall pay all costs of recalls and other corrective actions, including the costs of FDA's supervision, inspections, investigations, analyses, examinations, review, travel, and subsistence expenses to implement and monitor

recalls and other corrective actions, at the rates specified in paragraph 10 of this Decree.

12. Any cessation of operations as described in paragraph 11(A) shall be implemented immediately upon notice from FDA and shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with the Decree, the Act, and its implementing regulations. After a cessation of operations, and while determining whether Defendants are in compliance with the Decree, the Act, and its implementing regulations, FDA may require Defendants to re-institute or re-implement any of the requirements of this Decree.

13. If any Defendant fails to comply with the provisions of the Act, its implementing regulations, and/or this Decree, then Defendants shall pay to the United States of America liquidated damages in the sum of one thousand dollars (\$1,000.00) for each day that Defendants fail to comply with this Decree; an additional sum of five hundred dollars (\$500.00) in liquidated damages per day for each violation of the Act, its implementing regulations, and/or this Decree; and an additional sum equal to twice the retail value of each shipment of adulterated food. Defendants understand and agree that the liquidated damages specified in this paragraph are not punitive in nature and their imposition does not in any way limit the

ability of the United States to seek, and the Court to impose, additional criminal or civil penalties based on conduct that may also be the basis for payment of the liquidated damages.

14. If any Defendant violates this Decree and is found in contempt thereof, Defendants shall, in addition to other remedies, reimburse Plaintiff for its attorneys' fees, travel expenses incurred by attorneys and witnesses, expert witness fees, administrative and court costs, investigation and analytical expenses incurred in bringing the contempt action, and any other costs or fees related to the contempt proceedings.

15. All decisions specified in this Decree shall be vested in the discretion of FDA. FDA's decisions shall be final and, to the extent that these decisions are subject to review, shall be reviewed by the Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this Decree shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

16. Within ten (10) calendar days after entry of this Decree, Defendants shall provide a copy of this Decree to each and all of their officers, agents, employees, representatives, successors, assigns, heirs, attorneys, and any and all persons in active concert or participation with any of them (including

individuals, directors, corporations, subsidiaries, affiliates, and partnerships). Defendants shall provide to FDA within thirty (30) calendar days of the date of entry of this Decree, an affidavit of compliance with this paragraph stating the fact and manner of compliance and identifying the names and positions of all persons so notified.

17. Defendants shall prominently post a copy of this Decree in an employee common area at the facility within ten (10) calendar days of the entry of this Decree and shall ensure that the Decree remains posted for a period of at least six (6) months.

18. Defendants shall, within ten (10) calendar days of the entry of this Decree, hold a general meeting or series of smaller meetings for employees of the facility, at which they shall describe the terms and obligations of this Decree.

19. In the event that any Defendant becomes associated with any additional officers, agents, employees, representatives, successors, assigns, heirs, attorneys, or any additional persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) at any time after entry of this Decree, Defendants shall immediately provide a copy of this Decree, by personal service or certified mail (restricted delivery, return receipt requested), to such

persons. Within ten (10) calendar days of each instance that any Defendant becomes associated with any such additional persons, Defendants shall provide to FDA an affidavit stating the fact and manner of Defendants' compliance with this paragraph, identifying the names, addresses, and positions of all person who received a copy of this Decree pursuant to this paragraph, and attaching a copy of the executed certified mail return receipts. Within ten (10) calendar days of receiving a request from FDA for any information or documentation that FDA deems necessary to evaluate Defendants' compliance with this paragraph, Defendants shall provide such information or documentation to FDA.

20. Defendants shall address all communications with FDA required under this Decree to the Director, New York District Office, United States Food and Drug Administration, 158-15 Liberty Avenue, Jamaica, New York 11433, and shall reference this civil action by case name and civil action number in such communications.

21. This Court shall retain jurisdiction of this action and the parties hereto for the purpose of enforcing or modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.


SO ORDERED:

Dated this _____ day of _____, 2014.

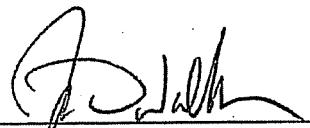
UNITED STATES DISTRICT JUDGE

We hereby consent to the entry of the foregoing Decree:

FOR DEFENDANTS



NANCY TABER RICHARDS
Individually and on behalf of
Finger Lakes Farmstead Cheese
Company, LLC

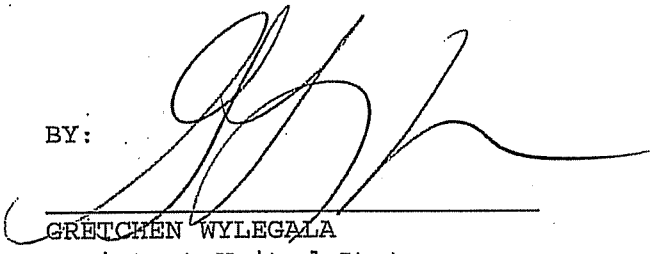


JEFFREY D. WALKER
Attorney for Finger Lakes
Farmstead Cheese Company, LLC

FOR PLAINTIFF

WILLIAM J. HOCHUL, JR.
United States Attorney

BY:



GRETCHEN WYLEGALA
Assistant United States
Attorney
United States Attorney's
Office
Western District of New York
138 Delaware Avenue
Buffalo, New York 14202

OF COUNSEL:

WILLIAM B. SCHULTZ

General Counsel

ELIZABETH DICKINSON
Associate General Counsel
Food and Drug Division

ANNAMARIE KEMPIC
Deputy Chief Counsel,
Litigation

MICHAEL SHANE
Associate Chief Counsel for
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